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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,496	04/12/2004	Larry F. Lemanski	6818-70	3665

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EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,496

Applicant(s)

LEMANSKI ET AL.

Examiner

Marsha M. Tsay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-24 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,7 and 10-14 is/are rejected.
- 7) ☒ Claim(s) 1,3,4 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 8, 2006, has been entered.

Claims 8-9 are canceled. Claims 5, 15-24 are withdrawn. Claims 1-4, 6-7, 10-14 are currently under examination.

Priority: The priority date is April 10, 2003.

Withdrawal of Objections and Rejections

The rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn. The amendment of the claims has introduced new issues under 35 U.S.C. 112, second paragraph, which appear below.

The rejection of claims 13-14 under 35 U.S.C. 103(a) as being unpatentable over Lemanski et al. (1996 Biochem Biophys Res Comm 229: 974-981; IDS) is withdrawn.

Claim Objections

Claims 1, 3 are objected to because of the following informalities: the apostrophe in SEQ ID NO's. should be deleted and the comma between SEQ ID NOS: 1, or 5 should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7, 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites said nucleotide sequence encodes an RNA molecule. As explained in the previous Office action, it is known in the art that the term "encodes" is used in the sense that DNA encodes protein. Since the instant claim recites RNA and not protein, it is suggested that another term be used to describe the transcription of the DNA to RNA. A possible suggestion is: The purified nucleic acid of claim 1, wherein said nucleotide sequence is transcribed into an RNA molecule having a secondary structure that permits specific binding to at least one MIR-binding protein.

Claim 7 recites a portion of said nucleotide sequence that is transcribed into a MIR molecule comprises a first polynucleotide sequence of SEQ ID NO: 5. The claim is confusing because it is unclear how large the nucleotide sequence can be if only a portion of the nucleotide sequence is transcribed into a MIR molecule, it is unclear the functional benefit of the remaining nucleotide sequence. Further, in their remarks, Applicants assert claim 7 has been amended to identify that SEQ ID NO: 5 contains an identical sequence corresponding to the 5' untranslated region of a second nucleic acid

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that encodes an RNA splicing factor, as identified by SEQ ID NOS: 6 and 7. However, this change is not reflected in the currently amended claim 7.

Claim 10 recites wherein said ribonucleic acid sequence is transcribed into a myofibrillogenesis-inducing RNA (MIR) molecule. The claim is confusing because it is believed that the RNA is already the MIR molecule. On page 5 of the instant specification, Applicants disclose the term "MIR" may also be used synonymously with the term "MIR RNA."

Claims 11-12 are included in this rejection because they are dependent on claim 10.

Claim 13 is drawn to a vector comprising a purified nucleic acid that is transcribed into a myofibrillogenesis-inducing RNA (MIR) molecule, SEQ ID NO: 5. The claim is confusing because it does not properly identify the nucleic acid sequence that is transcribed into the MIR molecule.

Claim 14 is included in this rejection because it is dependent on claim 13.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 1 be found allowable, claim 7 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 4 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 16, 2006

A handwritten signature in black ink that reads "Karen Cochrane Carlson Ph.D." The signature is written in a cursive, flowing style.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER